IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: John Miklos, M.D.)

Pending in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, is the *Daubert* Motion to Exclude or Limit Certain Opinions and Testimony of John Miklos, M.D. [ECF No. 4578] filed by defendant C. R. Bard, Inc. ("Bard"). The motion is now ripe for consideration because the briefing is complete. As set forth below, Bard's motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara

J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses, and replies were to be filed in the individual member cases. To the extent that an expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and

(1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct" – "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness"

> standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted). At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

III. Discussion

Dr. Miklos is a pelvic surgeon and urogynecologist who the plaintiffs offer as an expert witness. Bard objects to his testimony pertaining to general causation issues on several grounds, which I will address in turn.

A. Opinions Regarding Product Design

First, Bard argues that Dr. Miklos is not qualified to opine on the design of Align mesh products because he has no training or formal education in medical products design, and because he has never designed a mesh product or conducted relevant testing. *See* Bard's Mem. of Law in Supp. of Mot. to Limit or Exclude Certain Ops. & Test. of John Miklos, M.D. ("Bard's Mem. in Supp."), at 7-8 [ECF No. 4580]. In short, Bard contends, Dr. Miklos has no "training, education, or specialized knowledge regarding product design that sets him apart from the average urogynecologist." *Id.* at 8.

An expert may be qualified by "knowledge, skill, experience, training, or education[.]" Fed. R. Evid. 702. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989). Here, Dr. Miklos acknowledges that he is not an expert in the production of

biomaterials; rather, he believes himself to be an expert in the application of certain biomaterials in the human body. *See* Pls.' Reps. in Opp'n to Bard's Mot. to Exclude or Limit Certain Ops. & Test. of John Miklos, M.D. ("Pls.' Resp."), at 4-5 [ECF No. 4600] (citing *Id.*, Ex. A. ("Dr. Miklos Oct. 2014 Depo."), at 139:3-25). His clinical experience includes nearly twenty years implanting and explanting transvaginal mesh products. His professional and academic endeavors, which include consultations with companies providing design input into transvaginal mesh, further evinces clear qualifications to opine on the design of the Align devices within the scope of his experiences. I therefore **FIND** that Dr. Miklos is qualified to testify as an expert on the design of the Align product as it relates to its application in the human body.

Next, Bard argues that Dr. Miklos does not rely on sufficient facts or data and, therefore, the scientific methodology supporting his product design opinions is unreliable. Specifically, Bard challenges the conclusions Dr. Miklos reaches following its own independent analysis of his reported supporting evidence, which Bard believes is incomplete or inconsistent. Without more, this challenge is better suited on cross-examination. Accordingly, Bard's motion on this point is **DENIED**.

B. Opinions Regarding Warning Requirements and Product Labeling

In his expert report, Dr. Miklos opines that "Bard's failure to provide adequate and complete information to doctors," which he believes should have been communicated to surgeons in the mesh product's Instructions for Use ("IFU"), "prevented doctors and patients from reaching fully informed and educated decisions

about whether to use the Align products." *See* Bard's Mem. in Supp., Ex. B ("Dr. Miklos' Expert Repot"), at 19-23 [ECF No. 4578-2].

Seeking to exclude this opinion, Bard contends that Dr. Miklos lacks the necessary expertise to opine as an expert on the requirements of a product's IFU. Although Dr. Miklos has no experience drafting IFUs, he has demonstrated experience with the Align and the risks associated with its use. Based on this experience, I find him qualified to testify about whether the risks he perceives are in fact warned about in the IFU.

However, Dr. Miklos' opinion testimony on the IFU must stop there. *See In re: Ethicon Inc.*, No. 2327, 2016 WL 4944776, at *3 (S.D. W. Va. Aug. 26, 2016) ("While an expert who is a urologist or urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU"). In addition, Dr. Miklos cannot testify, "the omission of instructions or warnings" as set forth in his report, "rendered the Align products not reasonably safe." *See* Dr. Miklos' Expert Report, at 20. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *See, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."). An expert may not offer expert

testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008). Thus, to the extent that Dr. Miklos' opinions constitute legal conclusions or concern what an IFU should or should not include, those opinions are **EXCLUDED**. Bard's motion on this point is thus **DENIED in part** and **GRANTED in part**.

C. Opinions Regarding the Use of Polypropylene Mesh in Align Products

Next, Bard argues that Dr. Miklos is not qualified to offer any opinions on biomaterials because he has no experience manufacturing or designing mesh products, in addition to having never studied degradation or tested the tensile strength of pelvic mesh. *See* Bard's Mem. in Supp., at 14-15.

Bard, however, does not articulate how the absence of these experiences render Dr. Miklos unqualified, and provides little detail about the specific opinions at issue or why he is unqualified to offer them. I will not issue a blanket exclusion on all testimony about the use of polypropylene in the Align mesh products without more specificity. Bard's motion on this point is therefore **DENIED**.

D. Opinions Regarding Clinical Testing

Dr. Miklos also opines that "had Bard conducted, sponsored or funded clinical trials before putting the Align products on the market, the results would have shown [] the risks of implanting the Align product." Dr. Miklos' Expert Report, at 17. Bard objects to the admissibility of this opinion on grounds that Dr. Miklos is unqualified to opine on the adequacy of clinical trials and that his opinion lacks reliability. I agree.

Though it appears that his particular criticisms of the product itself and his investigations of patients presenting with mesh related complications are sufficiently supported and relevant, Dr. Miklos lacks sufficient expertise to present these conclusions by way of surmising the hypothetical results of a clinical trial. In other words, while the predicate findings may be admissible testimony, he is not qualified to extrapolate from these opinions the results of a theoretical clinical trial, and present that opinion as expert testimony. Accordingly, Bard's motion on this point is **GRANTED**.

E. Opinions on Bard's Knowledge, Motives, or Corporate Conduct

Finally, Bard argues that I should preclude Dr. Miklos from testifying as to Bard's knowledge or state of mind. I agree; experts may not testify about what other parties did or did not know. However, to the extent Bard seeks to exclude Dr. Miklos from testifying about factual issues or the knowledge of the medical community in general, I disagree. Expert witnesses may properly offer opinions on these topics. Therefore, the motion is **GRANTED** to the extent that it seeks to exclude evidence regarding Bard's knowledge or intent.

IV. Conclusion

For the reasons stated above, the court **ORDERS** that Bard's *Daubert* Motion to Exclude or Limit Certain Opinions and Testimony of John Miklos, M.D. [ECF No. 4578] is **GRANTED in part** and **DENIED in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the

Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 4, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.